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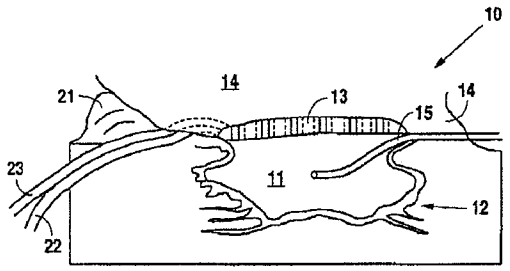
(54) SYSTEME DE FERMETURE DE PLAIE SOUS VIDE POURVU DE RECHAUFFEMENT ET DE REFROIDISSEMENT

(54) VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION

(57)

A method, and apparatus (10) for the controlled acceleration, and/or retardation of the body's inflammatory response generally comprises a foam pad (11) for insertion substantially into a wound site, a heating, a cooling pad (13) for application over the wound site (12), a wound drape (14) or sealing enclosure of the foam pad (11), the heating, and cooling pad (13) at wound site (12). The foam pad (11) is placed in fluid communication with a vacuum source for promotion of the controlled acceleration or retardation of the body's inflammatory response. The heating, and cooling provision controls the local metabolic function as part of the inflammatory response.



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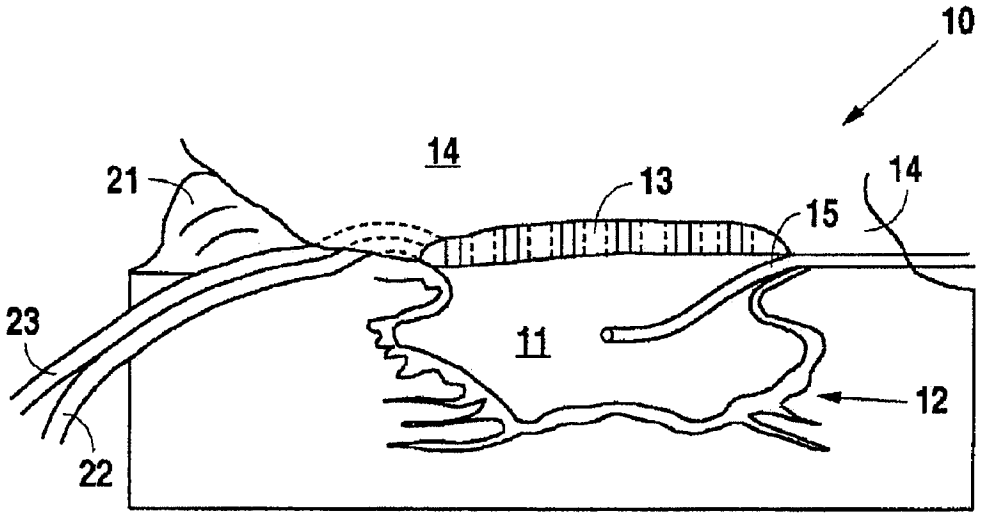

(57) Abrégé/Abstract:
A method, and apparatus (10) for the controlled acceleration, and/or retardation of the body's inflammatory response generally comprises a foam pad (11) for insertion substantially into a wound site, a heating, a cooling pad (13) for application over the wound site (12), a wound drape (14) or sealing enclosure of the foam pad (11), the heating, and cooling pad (13) at wound site (12). The foam pad (11) is placed in fluid communication with a vacuum source for promotion of the controlled acceleration or retardation of the body's inflammatory response. The heating, and cooling provision controls the local metabolic function as part of the inflammatory response.

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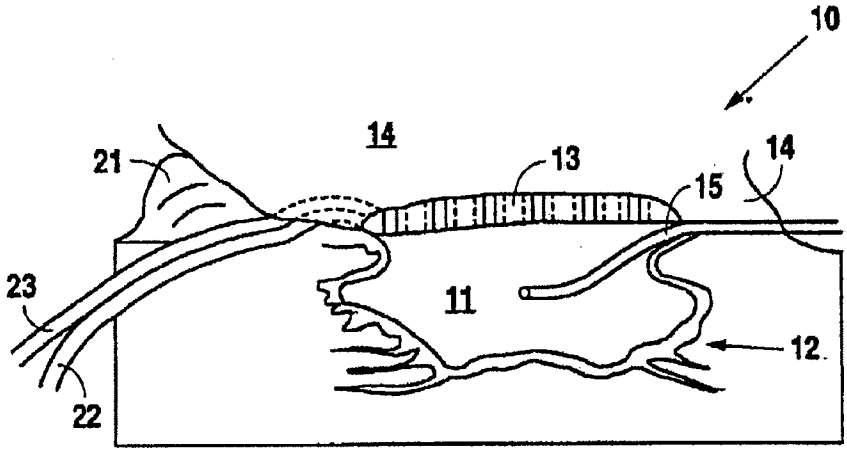

(57) Abstract

A method, and apparatus (10) for the controlled acceleration, and/or retardation of the body's inflammatory response generally comprises a foam pad (11) for insertion substantially into a wound site, a heating, a cooling pad (13) for application over the wound site (12), a wound drape (14) or sealing enclosure of the foam pad (11), the heating, and cooling pad (13) at wound site (12). The foam pad (11) is placed in fluid communication with a vacuum source for promotion of the controlled acceleration or retardation of the body's inflammatory response. The heating, and cooling provision controls the local metabolic function as part of the inflammatory response.

VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION

RELATED APPLICATION:

This application claims priority to United States provisional patent application Serial No. 60/127,596 entitled VACUUM ASSISTED CLOSURE SYSTEM WITH HEATING AND COOLING PROVISION filed April 2, 1999. By this reference, the full disclosure, including the drawings, of U.S. provisional patent application Serial No. 60/127,596 is incorporated herein.

TECHNICAL FIELD:

The present invention relates to the healing of wounds. More specifically, the present invention relates to the vacuum assisted closure of wounds wherein localized heating or cooling is used to accelerate or retard the metabolic function of the inflammatory system in order to facilitate wound healing.

BACKGROUND ART:

Wound closure involves the inward migration of epithelial and subcutaneous tissue adjacent the wound. This migration is ordinarily assisted through the inflammatory process, whereby blood flow is increased and various functional cell types are activated. Through the inflammatory process, blood flow through damaged or broken vessels is stopped by capillary level occlusion, whereafter cleanup and rebuilding operations may begin. Unfortunately, this process is hampered when a wound is large or has become infected. In such wounds, a zone of stasis (i.e. an area in which localized swelling of tissue restricts the flow of blood to the tissues) forms near the surface of the wound.

Without sufficient blood flow, the epithelial and subcutaneous tissues surrounding the wound not only receive diminished oxygen and nutrients, but are also less able to successfully fight bacterial infection and thus are less able to naturally close the wound. Until recently, such difficult wounds were addressed only through the use of sutures or staples. Although still widely practiced and often effective, such mechanical closure techniques suffer a major disadvantage in that they produce tension on the skin tissue adjacent the wound. In particular, the tensile force required in order to achieve closure using sutures or staples causes very high localized stresses at the suture or staple insertion point. These stresses commonly result in the rupture of the tissue at the insertion points, which can eventually cause wound dehiscence and additional tissue loss.

Additionally, some wounds harden and inflame to such a degree due to infection that closure by stapling or suturing is not feasible. Wounds not reparable by suturing or stapling generally require prolonged hospitalization, with its attendant high cost, and major surgical procedures, such as grafts of surrounding tissues. Examples of wounds not readily treatable with staples or suturing include large, deep, open wounds; decubitus ulcers; ulcers resulting from chronic osteomyelitis; and partial thickness burns that subsequently develop into full thickness burns.

As a result of these and other shortcomings of mechanical closure devices, methods and apparatus for draining wounds by applying continuous negative pressures have been developed. When applied over a sufficient area of the wound, such negative pressures have been found to promote the migration toward the wound of epithelial and subcutaneous tissues. In practice, the application to a wound of negative pressure, commonly referred to as vacuum assisted closure (VAC) therapy, typically involves mechanical-like contraction of the wound with simultaneous removal of excess fluid. In this manner, VAC therapy augments the body's natural inflammatory process while alleviating many of the known intrinsic side effects, such as the production of edema caused by increased blood flow absent the necessary vascular structure for proper venous return.

While VAC therapy has been highly successful in the promotion of wound closure, healing many wounds previously thought largely untreatable, some difficulty remains. Because the inflammatory process is very unique to the individual patient, even the addition of VAC therapy does not result in a fast enough response for closure of some wounds, especially when applied during the occlusion and initial cleanup and rebuilding stages. It is therefore a principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through controlled acceleration of the inflammatory response.

Additionally, and again at least partially attributable to the variance between patients, it is possible that a properly initiated inflammatory response may be taken too far, resulting in edema and pain. It is therefore another principle object of the present invention to provide a method and apparatus whereby the known VAC therapy modalities are improved through controlled retardation of the inflammatory response.

DISCLOSURE OF THE INVENTION:

In accordance with the foregoing objects, the present invention – a method and apparatus for the controlled acceleration and/or retardation of the body's inflammatory response – generally comprises a foam pad for insertion substantially into a wound site, a

heating and cooling pad for application over the wound site and a wound drape for sealing enclosure of the foam pad and the heating and cooling pad at the wound site. According to the invention, the foam pad is placed in fluid communication with a vacuum source for promotion of fluid drainage while warm or cool fluid is circulated through the heating and cooling pad for the controlled acceleration or retardation, respectively, of the metabolic function portion of the body's inflammatory response.

According to the preferred embodiment of the present invention, a heating and cooling provision is added to the previously known VAC therapy to control the local metabolic function as part of the inflammatory response. By providing localized heating in combination with the otherwise ordinary VAC therapy, the overall inflammatory response can be synergistically accelerated to produce rapid capillary occlusion and earlier initiation of the cleanup and rebuilding stages. Likewise, in the event that the attending clinician determines that the inflammatory response has been over-activated, localized cooling may be provided in combination with the VAC therapy to retard the body's inflammatory response without sacrifice of the edema control and other aspects of the otherwise provided VAC therapy.

In the preferred embodiment of the present invention, the heating and cooling pad comprises a flexible and breathable water layer, generally comprising two sheets of RF-weldable material. The two sheets of the pad are RF-welded together in a waffle-like pattern, wherein a plurality of apertures is formed between a plurality of channels. The apertures allow the transpiration of moisture from the patient's skin while the channels allow the circulation, via a supply tube and a drainage tube, of warm or cool water, as required, through the pad for the heating or cooling thereof.

While the heating and cooling pad may be placed inside or outside of the wound drape during the heating aspect of the present invention, it is critical that the heating and cooling pad be placed inside of the wound drape during the cooling aspect of the present invention. In this manner, condensate formation on the interior of the drape, which may cause the drape's adhesive to loosen and ultimately result in loss of vacuum at the wound site, can be minimized. In particular, placing the heating and cooling pad inside the wound drape limits the surrounding moisture content to that existing and generated within the confines of the wound site, which is minimized by the suction aspect of the VAC therapy.

Because the cooling aspect of the present invention should be implemented in this manner and the clinician may indicate the need for cooling at any time after initiation of VAC therapy, the preferred method of the present invention comprises placing the heating and cooling pad beneath the wound drape, adjacent the foam pad and wound site, regardless

of whether heating or cooling is initially indicated. Upon placement of the pad, the wound drape is firmly adhered about the supply tube and drainage tube to prevent vacuum leakage.

Finally, many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions, the following drawings and exemplary detailed description and the claims appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS:

Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiment follows together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

Figure 1 shows, in partially cut away perspective view, the preferred embodiment of the present invention as applied to a mammalian wound site; and

Figure 2 shows, in top cross-sectional plan view, the heating and cooling pad of the invention of Figure 1.

BEST MODE FOR CARRYING OUT THE INVENTION:

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention – a vacuum assisted closure system with heating and cooling provision, the scope of which is limited only by the claims appended hereto.

Referring now to the figures, the present invention 10 is shown to generally comprise a foam pad 11 for insertion substantially into a wound site 12, a heating and cooling pad 13 for application over the wound site 12 and a wound drape 14 for sealing enclosure of the foam pad 11 and the heating and cooling pad 13 at the wound site 12. According to the invention, the foam pad 11 is placed in fluid communication with a vacuum source for promotion of fluid drainage while warm or cool fluid is circulated through the heating and cooling pad 13 for the controlled acceleration or retardation, respectively, of the metabolic function portion of the body's inflammatory response.

According to the preferred embodiment of the present invention, the foam pad 11, wound drape 14 and vacuum source are implemented as known in the prior art, each of which is detailed in U.S. patent application Serial No. 08/517,901 filed August 22, 1995. By this reference, the full disclosure of U.S. patent application Serial No. 08/517,901 ("the '901 application"), including the claims and the drawings, is incorporated herein as though now

set forth in its entirety. Additionally, such a VAC system is readily commercially available through Kinetic Concepts, Inc. of San Antonio, Texas, U.S.A. and/or its subsidiary companies.

As detailed in the '901 application, the foam pad 11 preferably comprises a highly reticulated, open-cell polyurethane or polyether foam for good permeability of wound fluids while under suction. As also detailed in the '901 application, the foam pad 11 is preferably placed in fluid communication, via a plastic or like material hose 15, with a vacuum source, which preferably comprises a canister safely placed under vacuum through fluid communication, via an interposed hydrophobic membrane filter, with a vacuum pump. Finally, the '901 application also details the wound drape 14, which preferably comprises an elastomeric material at least peripherally covered with a pressure sensitive, acrylic adhesive for sealing application over the wound site 12.

According to the preferred method of the present invention, those components as are described in the '901 application are generally employed as known in the art with the exception that the heating and cooling provision of the present invention is added to control the local metabolic function as part of the inflammatory response. By providing localized heating in combination with the otherwise ordinary VAC therapy, the overall inflammatory response can be synergistically accelerated to produce rapid capillary occlusion and earlier initiation of the cleanup and rebuilding stages. Likewise, in the event that the attending clinician determines that the inflammatory response has been over-activated, localized cooling may be provided in combination with the VAC therapy to retard the body's inflammatory response without sacrifice of the edema control and other aspects of the otherwise provided VAC therapy.

In the preferred embodiment of the present invention, the heating and cooling pad 13 comprises a flexible and breathable water layer 16, generally comprising two sheets 17, 18 of RF-weldable material. The two sheets 17, 18 of the pad are RF-welded together in a waffle-like pattern, wherein a plurality of apertures 19 is formed between a plurality of channels 20. The apertures 19 allow the transpiration of moisture from the patient's skin 21 while the channels 20 allow the circulation, via a supply tube 22 and a drainage tube 23, of warm or cool water, as required, through the pad 13 for the heating or cooling thereof.

While the heating and cooling pad 13 may be placed inside or outside of the wound drape 14 during the heating aspect of the present invention, it is critical that the heating and cooling pad 13 be placed inside of the wound drape 14 during the cooling aspect of the present invention. In this manner, condensate formation on the interior and near the edges of the drape 14, which may cause the drape's adhesive to loosen and ultimately result in loss of

vacuum at the wound site 12, can be minimized. In particular, placing the heating and cooling pad 13 inside the wound drape 14 limits the surrounding moisture content to that moisture level existing and generated within the confines of the wound site 12, which is minimized by the suction aspect of the VAC therapy.

Because the cooling aspect of the present invention should be implemented in this manner and the clinician may indicate the need for cooling at any time after initiation of VAC therapy, the preferred method of the present invention comprises placing the heating and cooling pad 13 beneath the wound drape 14, adjacent the foam pad 11 and wound site 12, regardless of whether heating or cooling is initially indicated. Upon placement of the pad 13, the wound drape 14 is firmly adhered about the supply tube 22 and the drainage tube 23 to prevent vacuum leakage.

While the foregoing description is exemplary of the preferred embodiment of the present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description, the accompanying drawings and the claims drawn hereto. For example, those of ordinary skill in the art will recognize that the heating and cooling pad 13 may be constructed in a wide variety of shapes, sizes and internal structures. Such an alternative embodiment may comprise the integration of the heating and cooling pad 13 into a multi-layered version of the wound drape 14. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a limitation of the present invention, which is limited only by the claims appended hereto.

INDUSTRIAL APPLICABILITY:

The present invention is applicable to the wound healing arts.

CLAIMS:

What is claimed is:

1. A method for the promoting wound healing in mammals, said method comprising the steps of:

applying a vacuum to a region of a wound site on a mammal; and

effecting a change in the mammal's inflammatory response at said region while said vacuum is applied thereto.

2. The method for promoting wound healing as recited in claim 1, wherein said effecting a change step comprises controlling the mammal's local metabolic function at said region.

3. The method for promoting wound healing as recited in claim 2, wherein said effecting a change step comprises accelerating the mammal's local metabolic function at said region to encourage rapid capillary occlusion and accelerated initiation of the cleanup and rebuilding stages of the mammal's inflammatory response.

4. The method for promoting wound healing as recited in claim 3, wherein said effecting a change step comprises heating said region.

5. The method for promoting wound healing as recited in claim 2, wherein said effecting a change step comprises retarding the mammal's local metabolic function as said region to prevent over-activation of the mammal's inflammatory response.

6. The method for promoting wound healing as recited in claim 5, wherein said effecting a change step comprises cooling said region.

7. The method for promoting wound healing as recited in any of the preceding claims, wherein said applying a vacuum step comprises the steps of:

packing said wound site with a foam pad, said foam pad being in fluid communication with a vacuum source;

sealing said region, including said foam pad, with a wound drape; and

communicating said vacuum from said vacuum source through said foam pad to said region.

8. The method for promoting wound healing as recited in claim 7, wherein said effecting a change step comprises the steps of:

circulating a fluid about said region; and

controlling the temperature of said fluid to obtain said change.

9. The method for promoting wound healing as recited in claim 8, wherein said fluid is circulated about said region in a flexible envelope, said flexible envelope having an inlet and an outlet for fluid communication therethrough of said fluid.

10. The method for promoting wound healing as recited in claim 9, said method further comprising the step of sealing said flexible envelope, with said wound drape, between said foam pad and said wound drape.

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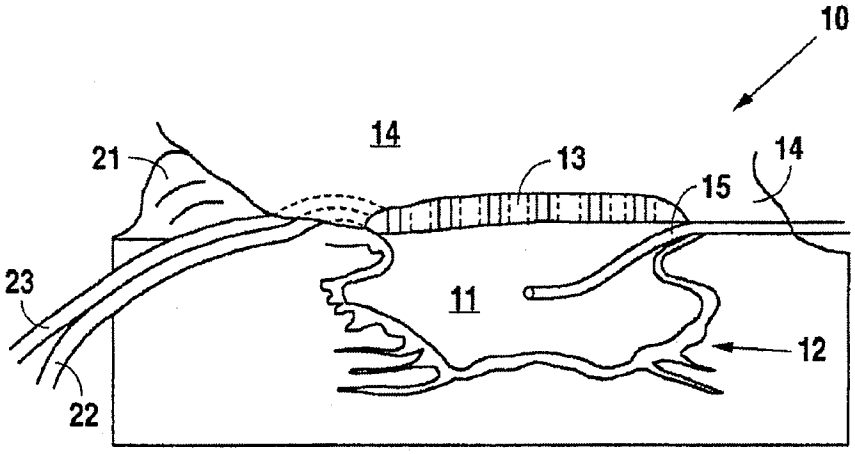

Fig. 1

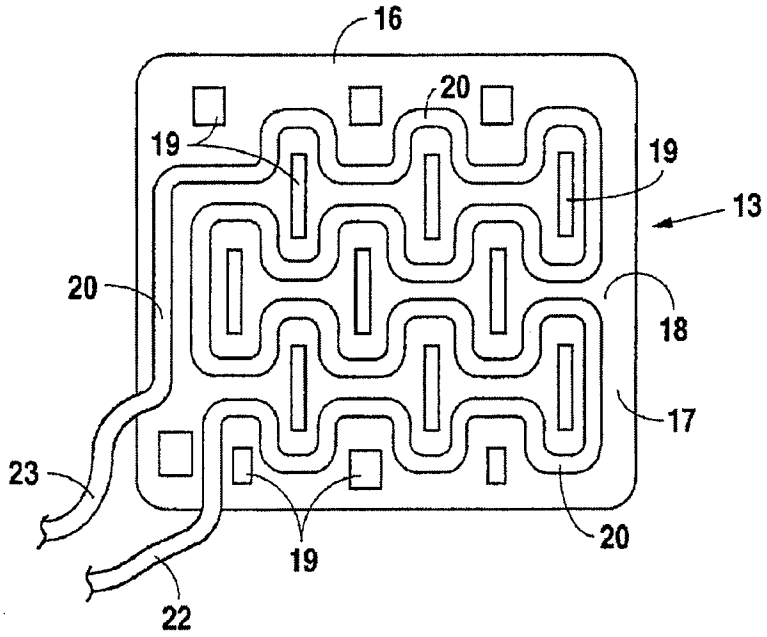

Fig. 2